NDA 019821/S-29

SUPPLEMENT APPROVAL

Stiefel Laboratories, Inc.
c/o GlaxoSmithKline
Attention: Linda Rebar - Director, Global Regulatory Affairs
1250 South Collegeville Road, PO Box 5089, Mail Code UP 4400
Collegeville, PA 19426-0989

Dear Ms. Rebar:

Please refer to your supplemental new drug application (sNDA) dated and received August 22, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Soriatane (acitretin) capsules.

This Prior Approval sNDA provides for revisions to the Prescribing Information (PI) and Do Your P.A.R.T. program.

The following were removed from the PI,Do Your P.A.R.T. Brochure and Medication Guide:

- Do Your P.A.R.T. Patient Survey
- Contraception Counseling Referral Program
- Authorization for Use or Disclosure of Health Information Form (Brochure only)

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Qianyiren Song, Regulatory Project Manager at 301-796-2581.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Do Your P.A.R.T. Brochure

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TATIANA OUSSOVA
02/22/2023 12:56:22 PM